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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,005	12/07/2001	Kurt L. Brillhart	2036-039	5606
22471	7590	02/26/2003		
BECKMAN COULTER INC 4300 NORTH HARBOR BOULEVARD P O BOX 3100 FULLERTON, CA 928343100			EXAMINER	CEPERLEY, MARY
			ART UNIT	PAPER NUMBER
			1641	
			DATE MAILED: 02/26/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/010,005	BRILLHART ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-12,14-21,23-30 and 32-36 is/are rejected.
- 7) Claim(s) 4,13,22, and 31 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other:   |

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**1)** The specification must be amended to include a section entitled "Brief Description of the Drawings".

**2)** The structure "3-dimethylamino-2-methylpropyl chloride" of Figure 1 is missing a hydrogen atom on the second carbon from the right.

**3)** The Abstract must be amended to indicate the type of "additive", the alleged point of novelty of the invention.

**4)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**5)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**6)** Claims 1-3, 6-12, 15-21, 24-30, and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** The use of the term "substituted alkyl" renders the claims indefinite for the reasons that **a)** it is unclear as to what "substituents" are meant to be included and **b)** the exact scope of the claims cannot be determined. Page 11, lines 25-30 of the specification gives *examples* of appropriate substituents for alkyl groups but does not provide any *definitive list* of suitable substituents. Although this section of the specification states that "the substituents of the substituted alkyl groups include, *for example*, hydroxy,...and halogens", this section does not specify what features or functions these substituents have

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in common such that one skilled in the art could determine what additional "substituents" might be intended.

**b)** The compound "N,N-dimethylguanidine" of claim 3 contains a -C=NH- group. The compounds of the structure of step (iii) of claim 1 do not contain a -C=NH- group. The structure of "guanidine" is  $(H_2N)_2C=NH$ . The structure of "N,N-dimethylguanidine" of Figure 1 appears to be in error.

**7)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**8)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**9)** Claims 1-3, 5-12, 14-21, 23-30, and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Ito et al (U.S. 5,486,479) or Ito et al (U.S. 5,506,151).

Each of the references describes a particle agglutination assay in which particles having immobilized analyte-specific binding partner are reacted with an analyte-containing test sample in the presence of an amine-containing non-specific reaction suppressor followed by a determination of the binding of the analyte and its binding partner as a measure of the presence/amount of analyte in the sample. The non-specific reaction suppressors of the references include compounds which correspond to the compounds of the formula (iii) of instant claim 1. These methods anticipate the method of instant

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claim 1. See Ito et al ('479): col. 3, lines 13-24; col. 2, lines 54-55; col. 7, lines 58-62; col. 8, lines 1-28; claims 1, 13 and 19; Ito et al (U.S. 5,506,151): Fig. 5; col. 5, lines 51-67; col. 3, lines 7-36; Table 1.

For the kit and composition of instant claims 21 and 29 see, for example, Ito et al ('151), col. 5, lines 63-67; claim 1; Ito et al ('479), claim 1.

For the indirect assay format of instant claim 10 and other conventional immunoassay formats see Ito et al ('151), col. 5, lines 51-62; col. 1, line 60 – col. 2, line 4; Ito et al ('479), col. 2, line 63 – col. 3, line 13.

For a compound corresponding to an "additive" of claim 3, see Ito et al ('151), the structure of col. 3, line 10 wherein R<sub>1</sub>, R<sub>2</sub> = methyl; -(CHY)<sub>m</sub>- = -CH<sub>2</sub>-; -(CHY)<sub>p</sub>- = -CH(CH<sub>3</sub>)-; R<sub>3</sub> = -NH<sub>2</sub>; n = 0. (see also "Dimethylaminopropylamine" of Table 1 of col. 9). This is the compound "1-dimethylamino-2-propylamine" of Figure 1 of the instant specification.

For the additive "3-dimethylamino-2-methylpropyl chloride" of instant claim 5, see Ito et al, the compound of col. 3, line 10 wherein R<sub>1</sub>, R<sub>2</sub> = -CH<sub>3</sub>; -(CHY)<sub>m</sub>- = -CH<sub>2</sub>-; -(CHY)<sub>p</sub>-R<sub>3</sub> = -CH(CH<sub>3</sub>)-CH<sub>2</sub>Cl.

The characterization of the "additive" of instant claim 1 as having the effect of "reducing non-specific aggregation of said particles" does not differentiate these "additives" from the compounds used in the prior art references which have the same "non-specific reaction suppressor" effects when used in an immunoassay. Further, independent of any specific characterization/description of the "additive" of instant claim 1, the method of the instant claim 1 is inherently the same method as the methods of the prior art references, i.e. the same reagents, additives and method steps are used in both the instantly claimed immunoassays and those of the prior art.

**10)** Claims 1-3, 5-12, 14-21, 23-30, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Ito et al (U.S. 5,486,479) or Ito et al (U.S. 5,506,151).

The Ito et al references are applied for the reason stated in the above rejection under 35 USC 102(b). The features of the independent and dependent claims are either specifically described by the references or constitute obvious variations in parameters which are routinely modified in the art and

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which have not been described as critical to the practice of the invention. For example, for the latex particles of instant claim 33, see Ito et al ('151), col. 6, line 31; for the equivalence of a variety of analytes such as those described in instant claim 35, see Ito et al ('151), the table of "immunoreactants" of col. 4; for the concentration of "additive" of instant claim 36, see Ito et al ('151), col. 4, line 25 "0.1 to 300mM".

**11)** Claims 4, 13, 22, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**12)** Shigenobu et al (Chemical Abstract document no. 136 : 83390) is cited to further show the state of the art.

**13)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

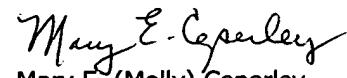
Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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February 25, 2003



Mary E. (Molly) Ceperley

Primary Examiner

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